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CONFIRMATION NO. APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 21819-119CONCON 8291 10/706,525 11/12/2003 Marwan Abboud 12/08/2005 EXAMINER 31292 7590 CHRISTOPHER & WEISBERG, P.A. PEFFLEY, MICHAEL F 200 EAST LAS OLAS BOULEVARD PAPER NUMBER ART UNIT **SUITE 2040** FORT LAUDERDALE, FL 33301 3739

DATE MAILED: 12/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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| | | Application No. | Applicant(s) | | |
|--|---|---|--|--|--|
| | 10/706,525 | ABBOUD ET AL. | | | |
| | Office Action Summary | Examiner | Art Unit | | |
| | Michael Peffley | 3739 | | | |
| 7 Period for F | The MAILING DATE of this communication (Reply | appears on the cover sheet with the | e correspondence address | | |
| WHICHI - Extensio after SIX - If NO per - Failure to Any reply | RTENED STATUTORY PERIOD FOR REI EVER IS LONGER, FROM THE MAILING ns of time may be available under the provisions of 37 CFR (6) MONTHS from the mailing date of this communication. riod for reply is specified above, the maximum statutory per or reply within the set or extended period for reply will, by state by received by the Office later than three months after the material term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNICATION 1.136(a). In no event, however, may a reply be od will apply and will expire SIX (6) MONTHS froute, cause the application to become ABANDO | ON. It timely filed om the mailing date of this communication. NED (35 U.S.C. § 133). | | |
| Status | | | | | |
| 1)⊠ R | esponsive to communication(s) filed on 12 | November 2003 | | | |
| • | This action is FINAL . 2b)⊠ This action is non-final. | | | | |
| · | 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| | · | r en pario quayro, roco o.e. rr, | 100 0.0. 210. | | |
| Disposition | of Claims | | | | |
| 4)⊠ CI | 4) Claim(s) 13-23 is/are pending in the application. | | | | |
| 4a | 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | |
| 5) <u></u> CI | aim(s) is/are allowed. | | | | |
| 6)⊠ CI | aim(s) <u>13-23</u> is/are rejected. | | | | |
| 7)□ CI | aim(s) is/are objected to. | | • | | |
| 8)∏ CI | aim(s) are subject to restriction and | d/or election requirement. | | | |
| Application | Papers | | | | |
| 9)∐ Th | e specification is objected to by the Exam | iner. | | | |
| 10)⊠ The drawing(s) filed on <u>12 November 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| · | · | | | | |
| _ | ler 35 U.S.C. § 119 | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | |
| Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
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| | | | | | |
| Attachment(s) | | | | | |
| _ | f References Cited (PTO-892) | 4) Interview Summa | nn (PTO-413) | | |
| 1) 🔀 Notice of References Cited (PTO-892) 4) 🔲 Interview Summary (PTO-413) Paper No(s)/Mail Date | | | | | |
| 3) 🔲 Informati | ion Disclosure Statement(s) (PTO-1449 or PTO/SB/ | 08) 5) Notice of Informa | Patent Application (PTO-152) | | |
| Paper No | o(s)/Mail Date | 6) Other: | | | |

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Preliminary Amendment

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Applicant's preliminary amendment filed November 12, 2003 indicates that claims 13-32 are canceled in favor of newly added claims 33-43. However, it is noted that the instant application is a continuation of US Serial No. 10/202,991, which application was originally filed with claims 1-12. During prosecution of the '991 application, claims 1-12 were canceled in favor of claims 13-32. However, the instant application being a continuation of the '991 application is filed as a copy of the <u>originally filed</u> '991 application, and therefore includes the originally filed claims 1-12. As such, the newly added claims 33-43 (filed with the amendment of November 12, 2003) have been renumbered as claims 13-23, and the remaining claims (i.e. original claims 1-12) have been canceled as was apparently applicant's intention. Applicant's response to this Office action should acknowledge and make official the cancellation of claims 1-12, and should also reflect the renumbering of claims 33-43 as claims 13-23.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 13-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Neilson et al (5,733,319).

Neilson et al disclose a catheter system comprising a handle portion (30 – Figure 2A) having first and second flow paths (94B,96B), and a flexible catheter (32) having proximal and distal ends, with the proximal end (50) connected to the handle. The catheter includes first and second fluid paths (64A, 66A) which are connected to the first and second fluid paths of the handle to deliver and return a cooling fluid to the catheter distal end. A pressure sensor (130) is provided that communicates the pressure of fluid in the fluid pathway (see Abstract). The pressure sensor is used to control the fluid delivered to the system (Abstract). As discussed at column 12 of the Neilson et al. patent, a control system allows for the control of the delivery of the fluid based on the monitored temperature and/or pressure of the fluid in the circulation system. The control system is also inherently operable to terminate delivery of the fluid (i.e. if an errant temperature/pressure is detected). Also, leaks anywhere along the fluid path (i.e. handle or flow paths) would inherently show up as variations in pressure at the pressure sensor. The pressure at the distal end of the return lumens is inherently less than the pressure at the supply lumen inlet.

Claims 13-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Lalonde et al (6,283,959).

Lalonde et al disclose a catheter system including a handle and a flexible catheter (Figure 1). The handle includes first (40a) and second (40b) fluid flow paths

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that are connected to the inlet and outlet (i.e. first and second) paths in the catheter.

Lalonde et al specifically teach that a pressure sensor (51) may be provided in the fluid flow path to monitor the fluid pressure in the system (see col. 5, lines 25-36). The pressure sensing arrangement is used to send a feedback signal to control the delivery of the coolant. The examiner maintains that such a system is inherently operative to terminate delivery upon sensing an errant reading as is generally well-known in the art. Further, a leak anywhere in the system would inherently provide errant reading that would be detected at the pressure sensing arrangement. The pressure of the coolant in the supply side is much higher than the return pressure of the coolant.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 13-23 are rejected on the ground of nonstatutory obviousness-type

double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,440,126.

Although the conflicting claims are not identical, they are not patentably distinct from

each other because claims 13-23 recite a broader, but substantially identical system to

that set forth in the '126 patented claims.

Claims 13-23 are rejected on the ground of nonstatutory obviousness-type

double patenting as being unpatentable over claims 1-20 of U.S. Patent No. 6,746,445.

Although the conflicting claims are not identical, they are not patentably distinct from

each other because claims 13-23 recite a broader, but substantially identical system to

that set forth in the '445 patented claims.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lalonde et al (6,383,180) discloses another cryocatheter system

that includes plurality flow paths and a pressure sensor to monitor system conditions.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Michael Peffley whose telephone number is (571) 272-

4770. The examiner can normally be reached on Mon-Fri from 6am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number

for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael Peffley

Primary Examiner Art Unit 3739

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December 2, 2005